

§ 660.4 Potency test.

To be satisfactory for release, each filling of Antibody to Hepatitis B Surface Antigen shall be tested against the Reference Hepatitis B Surface Antigen Panel and shall be sufficiently potent to detect the antigen in the appropriate sera of the reference panel by all test methods recommended by the manufacturer in the package insert.

[40 FR 29711, July 15, 1975]

§ 660.5 Specificity.

Each filling of the product shall be specific for antibody to hepatitis B surface antigen, as determined by specificity tests found acceptable by the Director, Center for Biologics Evaluation and Research.

[40 FR 29712, July 15, 1975, as amended at 49 FR 23834, June 8, 1984; 55 FR 11013, Mar. 26, 1990]

§ 660.6 Samples; protocols; official release.

(a) *Samples.* (1) For the purposes of this section, a sample of product not iodinated with ¹²⁵I means a sample from each filling of each lot packaged as for distribution, including all ancillary reagents and materials; and a sample of product iodinated with ¹²⁵I means a sample from each lot of diagnostic test kits in a finished package, including all ancillary reagents and materials.

(2) Unless the Director, Center for Biologics Evaluation and Research, determines that the reliability and consistency of the finished product can be assured with a smaller quantity of sample or no sample and specifically reduces or eliminates the required quantity of sample, each manufacturer shall submit the following samples to the Director, Center for Biologics Evaluation and Research (HFB-1), 8800 Rockville Pike, Bethesda, MD 20892, within 5 working days after the manufacturer has satisfactorily completed all tests on the samples:

(i) One sample until written notification of official release is no longer required under paragraph (c)(2) of this section.

(ii) One sample at periodic intervals of 90 days, beginning after written notification of official release is no

longer required under paragraph (c)(2) of this section. The sample submitted at the 90-day interval shall be from the first lot or filling, as applicable, released by manufacturer, under the requirements of § 610.1 of this chapter, after the end of the previous 90-day interval. The sample shall be identified as "surveillance sample" and shall include the date of manufacture.

(iii) Samples may at any time be required to be submitted to the Director, Center for Biologics Evaluation and Research, if the Director finds that continued evaluation is necessary to ensure the potency, quality, and reliability of the product.

(b) *Protocols.* For each sample submitted as required in paragraph (a)(1) of this section, the manufacturer shall send a protocol that consists of a summary of the history of manufacture of the product, including all results of each test for which test results are requested by the Director, Center for Biologics Evaluation and Research. The protocols submitted with the samples at periodic intervals as provided in paragraph (a)(2)(ii) of this section shall be identified by the manufacturer as "surveillance test results."

(c) *Official release.* (1) The manufacturer shall not distribute the product until written notification of official release is received from the Director, Center for Biologics Evaluation and Research, except as provided in paragraph (c)(2) of this section. Official release is required for samples from at least five consecutive lots or fillings, as applicable, manufactured after licensure of the product.

(2) After written notification of official release is received from the Director, Center for Biologics Evaluation and Research, for at least five consecutive lots or fillings, as applicable, manufactured after licensure of the product, and after the manufacturer receives from the Director, Center for Biologics Evaluation and Research, written notification that official release is no longer required, subsequent lots or fillings may be released by the manufacturer under the requirements of § 610.1 of this chapter.

(3) The manufacturer shall not distribute lots or fillings, as applicable, of